

REMARKS

Claims 9 to 29 as amended and new Claims 30 to 36 are present for purposes of prosecution.

Claims 1 to 8 have been withdrawn and are now cancelled.

Claims 19 to 29 are allowed.

Claims 11 to 18 are objected to as containing elected and non-elected subject matter.

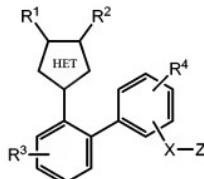
Claims 11 to 18 are also rejected for depending on a rejected base claim. The Examiner indicates that "Claims drawn solely to the elected invention as identified, supra, would appear allowable".

Claims 9 and 10 are rejected under 35 U.S.C. §112, first paragraph.

Reconsideration of the rejection of this application is respectfully requested in view of the above amendments and the following remarks.

Amendments to Claims

New independent Claim 30 has been added to cover the method as defined in original Claims 9 and 11 wherein the elected and examined subject matter that is

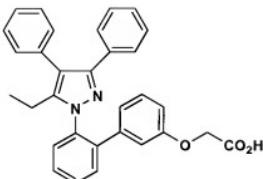


wherein Het represents a 1,2-diazole group, R<sup>1</sup> and R<sup>2</sup> are each independently substituted or unsubstituted aryl group and X and Z are as previously defined. Thus, Claim 30 is essentially original Claim 9 wherein Het, R<sup>1</sup>, R<sup>2</sup>, X and Z are as defined above.

New Claims 31 to 36 correspond to original Claims 12, 13, 15 to 18, respectively.

Claim 11 has been amended so that it is a combination of original Claims 9 to 11.

Applicants affirm their election of Claims 9 to 29 drawn to a method of recovering a drug substance from a liquid medium and where Applicants "elected palladium species, polystyrene resin as solid extract species; tetrahydrofuran as liquid species; and



as a drug substance species."

The Examiner indicates that

"As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 9-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as triazine, homopiperazinyl, thiomorpholinyl, propylaminyl etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 63(+) (thiomorpholine), class 540 subclass 450(+) (homopiperziny), class 544 subclass 180(+) (triazines), 548 subclass 400(+) pyrrolidines etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive."

As indicated, new Claims 30 to 36 now define elected and examined subject matter.

It is submitted that the Examiner should examine Claims 9 and 11 as amended (and claims dependent thereon) as well.

The present application contains linking Claims 9 and 11 which, if allowable, requires rejoinder. Claims 9 and 11 are genus claims which link species Claims 19 to 29 and new species Claims 30 to 36. Since the Examiner has indicated that Claims 19 to 29 are allowed, Claims 30 to 36 define the invention which the Examiner indicates as "elected and examined". These claims apparently contain allowable subject matter since no prior art has been cited. Therefore, it would appear that the invention as defined in these claims contain patentable subject matter.

As indicated in MPEP §809, column 2, second full paragraph

"The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the non-elected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability. Where the requirement for restriction in an application is predicted upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions...."

In view of the above, it is submitted that Claims 9 and 11, and Claims 10 and 12 to 18 should be examined.

#### **Claim Rejections – 35 USC §112, First Paragraph**

Claims 9 and 10 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner contends that

"Claim [1] 9 is directed to a method of recovering a drug substance from a liquid medium wherein the drug substance is not defined by any Formula."

The Examiner analyzes the rejection as follows:

##### **Nature of the invention.**

The claims are drawn to a method recovering a drug substance from a liquid medium wherein the drug substance is not defined by any Formula.

##### **State of the prior art.**

There are several drug substances that have different structures.

##### **Level of ordinary skill in the art.**

The level of ordinary skill in the art is high. The term drug substance is broad and encompasses a vast number of compounds. Applicant's specification does not enable the public to use the method of extraction for all drug substances.

##### **Amount of direction and guidance provided by the inventor.**

The term 'drug substance' encompasses a vast number compounds and compositions. Applicant's limited guidance does not enable the public to prepare such a numerous amount of compounds by the instant process.

##### **Existence of working examples.**

The genus encompasses a vast number of drug substances. Applicant's limited working examples do not enable the public to recover all drug substances by the instant process. Applicant claims a method for recovering a plethora of drug substances, however, the specification provides only limited examples of the instant process.

##### **Quantity of experimentation needed to make or use the invention based on the content of the disclosure.**

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain compounds as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentations, see *In re Armbruster* 185 USPQ 152 CCPA 1975.

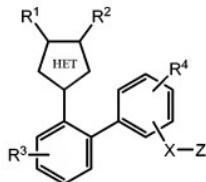
It is suggested to include the Formula of the drug substance contemplated in claim 9."

Claim 11 has been amended so that it is a combination of Claim 9 and 11 and defines the drug substance as in original Claim 11.

Claim 9 remains without inclusion of a formula of the drug substance.

The principle behind the present invention as defined in Claims 9 and 11 is not limited to any particular drug substance, but is directed to a method of recovering a drug substance from a liquid medium containing the drug substance together with at least one metal, the method residing in contacting the liquid medium with a solid extractant having a metal-binding functionality, the metal-binding functionality containing an unsubstituted or substituted phosphine group the metal-binding functionality being connected to the solid extractant directly or via a linking moiety which does not include at least one of a hydrocarbysilyl residue or a polyamine residue; and separating the drug substance from the liquid medium.

In Claim 11, the drug substance is defined as



The drug substance is defined in the Specification at pages 10 to 13. Lists of drug substances that can be used in the method of the invention are set out at pages 25 to 32 of the Specification. A discussion of the preparation of compounds defined in Claim 11 is set out at pages 47 to 55 of the Specification. The Specification includes a comprehensive disclosure of solid extractants, linkers and phosphines at pages 13 to 16 and liquids at pages 23 and 24 and metals which can be removed at pages 17 to 23 of the Specification.

The Specification includes Examples 1 to 32 which teach how to remove the elected drug substance from a liquid containing a metal. It will be apparent to one skilled in the art that the technology disclosed in the working Examples has general applicability to removing any of the drug substances set out at pages 25 to 32 of the Specification from liquids containing metals.

In view of the above, it is submitted that the Specification is an enabling disclosure which would teach one skilled in the art to remove a drug substance, including the drug substances disclosed herein, from a liquid containing a metal. Accordingly, since the invention resides in the steps defined in the claims which are generally applicable to the drug substances disclosed herein,

it is submitted that broad terminology with respect to the methods as defined in Claims 9 and 11 are in compliance with 35 USC §112, first paragraph. In re Smythe, 178 USPP 279 (CCPA 1973).

**Conclusions**

Claims 19 to 29 are allowed.

Claims 30 to 36 define the invention to include the elected and examined subject matter and would appear to be in condition for allowance as well.

Claims 9 and 11 (and claims depending thereon) are linking claims to allowable species claims and thus should be examined in this application.

Claims 9 and 10 are in compliance with 35 USC §112, first paragraph for the reasons set out above.

In view of the foregoing it is submitted that Claims 9 to 29 and 30 to 36 are in condition for allowance.

Respectfully submitted,

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